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May 4, 2004

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BY ELECTRONIC AND REGULAR MAIL

Ms. Kathleen Ellwood
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and
Dietary Supplements
CFSAN, U.S. Food and Drug Administration
Room 4A026, HFS-830
5100 Paint Branch Parkway
College Park, MD 20740

Re: Health Claim Petition: Dietary supplementation of Crystalline Glucosamine Sulfate (Glucosamine Sulfate Sodium Chloride-USP/NF 2003) reduces the risk of osteoarthritis.

Dear Ms. Ellwood:

You asked whether we would agree to extend the review period of the above-referenced health claim petition submitted by our client, Rotta Pharmaceuticals Inc., on September 17, 2003. FDA accepted the petition for filing on February 13, 2004. Within 90 days of accepting a petition for filing (*i.e.*, May 13th), FDA must notify the petitioner whether it will deny the health claim petition or issue a proposed regulation regarding the requested health claim. 21 C.F.R. § 101.70(j)(3).

The agency is convening a food advisory committee (FAC) on June 7th and 8th to discuss the issues raised in the above-referenced petition. FDA has asked that we provide an additional 60 days after the FAC (*i.e.*, until August 6th) for the agency to reach its decision on whether it will deny the health claim petition or issue a proposed regulation authorizing the use of claims regarding the role of crystalline glucosamine sulfate in reducing the risk of osteoarthritis. We agree to extend the review period until August 6, 2004.

If you have any questions, please contact us.

Sincerely,

Martin J. Hahn

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